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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/642,638 | 08/19/2003 | Howard R. Levin | 3659-70 | 3724 |

23117 7590 09/21/2004

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EXAMINER

DEAK, LESLIE R

ART UNIT

PAPER NUMBER

3762

DATE MAILED: 09/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/642,638

Applicant(s)

LEVIN ET AL.

Examiner

Leslie R. Deak

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 August 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 49-69 is/are pending in the application.
- 4a) Of the above claim(s) 49-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 55-69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 49-69 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 8/19/03, 4/27/04.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 49-54, drawn to a fluid removal apparatus with a membrane of specific porosity, classified in class 604, subclass 6.09.
- II. Claims 55-69, drawn to a fluid removal apparatus with a particular filter surface area, classified in class 604, subclass 6.09.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions in Group I and Group II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the porosity of the filter membrane does not require the particular surface area of the subcombination fluid removal apparatus. The subcombination has separate utility such as use in a fluid separation system that filters larger or smaller particles than those filtered by the combination with a specific porosity.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. During a telephone conversation with Jeffry Nelson on 17 September 2004, a provisional election was made without traverse to prosecute the invention of Group II, claims 55-69. Affirmation of this election must be made by applicant in replying to this Office action. Claims 49-54 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

6. Claim 56 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 56 recites the same active filter membrane surface as set out in claim 55.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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8. Claims 66-69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The preamble of the claims refer to a method, but the parent claim is a device claim.

9. With regard to claim 66, the amount of blood contained in "less than two percent of a cardiac output of an adult" is vague. Since cardiac output varies from patient to patient, the metes and bounds of the claim cannot be determined.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 55, 56, 58, 60, 62, 64, 65, 67, 68 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,211,850 to Shettigar et al. Shettigar discloses a blood filter that removes blood from a patient, runs it through a filter, and returns filtered blood to the patient. The internal surface area of the filter may be between 0.1 and 5.0 m², the length of the fibers may be 20-25 cm², and the flow rate of the blood through the filter may be 50-3000 mL/min. With regard to the diameter of the fiber bundle, Shettigar discloses that the preferred embodiment of the device has a fiber length of 20cm, and illustrates an embodiment that shows the diameter of the fiber bundle to be less than

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1/13th of the length of the fibers, indicating that the diameter of the bundle is less than 1.5cm.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 57, 59, 61, 63, and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,211,850 to Shettigar. Shettigar discloses the claimed apparatus as explained above, but does not disclose the number of fibers, or the shear rate of the blood flow therethrough. However, Shettigar discloses that the filter dimensions, flow rate, blood shear rate, and transmembrane pressure are all interrelated in the art of blood filtration. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to adjust the dimensions, flow rate, and shear rate of the procedure and device via manipulation of the transmembrane pressure in order to effectively filter the blood according to the desired outcome.

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Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

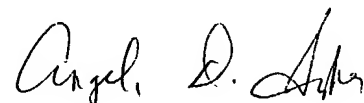
- a. US 5,928,180 Kritiviski et al
 - i. Blood filtration system that monitors fluid level in system

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 703-305-0200. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lrd
17 September 2004



ANGELA D. SYKES
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